

## DETAILED ACTION

### *Election/Restrictions*

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-4, drawn to a method of regulating apoptosis comprising introducing into a cell a RNA construct comprising a nucleotide sequence which is homologous to Bcl-2.

Group II, claim(s) 1-2, and 5-6, drawn to a method of regulating apoptosis comprising introducing into a cell an RNA construct comprising a nucleotide sequence which is homologous to Bcl-xL.

Group III, claim(s) 1-2 and 7, drawn to a method of regulating apoptosis comprising introducing into a cell an RNA construct comprising a nucleotide sequence which is homologous to a viral homologue of a gene involved in the regulation of apoptosis.

Group IV, claim(s) 8-12, and 17, drawn to an siRNA construct which is homologous to SEQ ID NO: 7 or 9.

Group V, claim(s) 8-10, 13-14, and 17 drawn to an siRNA construct which is homologous to SEQ ID NO: 11.

Group VI, claim(s) 15-16, 18-19, drawn to a method treating a disease or condition comprising administering a construct targeting Bcl-2.

Group VII, claim(s) 15-16, 18-19, drawn to a method treating a disease or condition comprising administering a construct targeting Bcl-xL.

Group VIII, claim(s) 15 and 20, drawn to a method treating a disease or condition comprising administering a construct targeting a viral inducer of cancer.

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2. The inventions listed as Groups I-VIII do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: Groups I-VIII are drawn to multiple methods and products used in said methods, thus the claims are drawn to multiple categories of invention as defined in 37 CFR § 1.475(b). Therefore, the inventions of Groups I-VIII are considered to lack unity of invention as per 37 CFR 1.475 § (c), set forth below:

37 CFR § 1.475 Unity of invention before the International Searching Authority, the International Preliminary Examining Authority and during the national stage.

(a) An international and a national stage application shall relate to one invention only or to a group of inventions so linked as to form a single general inventive concept ("requirement of unity of invention"). Where a group of inventions is claimed in an application, the requirement of unity of invention shall be fulfilled only when there is a technical relationship among those inventions involving one or more of the same or corresponding special technical features. The expression "special technical features" shall mean those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art.

(b) An international or a national stage application containing claims to different categories of invention will be considered to have unity of invention if the claims are drawn only to one of the following combinations of categories:

- (1) A product and a process specially adapted for the manufacture of said product; or
  - (2) A product and process of use of said product; or
  - (3) A product, a process specially adapted for the manufacture of the said product, and a use of the said product; or
  - (4) A process and an apparatus or means specifically designed for carrying out the said process; or
  - (5) A product, a process specially adapted for the manufacture of the said product, and an apparatus or means specifically designed for carrying out the said process.
- (c) If an application contains claims to more or less than one of the combinations of categories of invention set forth in paragraph (b) of this section, unity of invention might not be present.
- (d) If multiple products, processes of manufacture or uses are claimed, the first invention of the category first mentioned in the claims of the application and the first recited invention of each of the other categories related thereto will be considered as the main invention in the claims, see PCT Article 17(3)(a) and § 1.476(c).
- (e) The determination whether a group of inventions is so linked as to form a single general inventive concept shall be made without regard to whether the inventions are claimed in separate claims or as alternatives within a single claim.

3. Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

4. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Janet L. Epps-Ford whose telephone number is 571-272-0757. The examiner can normally be reached on M-F, 10:00 AM through 6:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Weitach can be reached on 571-272-0739. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Janet L. Epps-Ford/  
Primary Examiner, Art Unit 1633